



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

11/19/01 12:00 PM

OCT 21 2002

Mr. Kenneth F. Lind
President
Vital Living
5080 North 40th Street
Suite 105
Phoenix, Arizona 85018-2147

Dear Mr. Lind:

This is in response to your letter of September 26, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Essentium**[®] uses the claim "...supporting LDL..." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claim for your product, that is, the claim about supporting low density lipoprotein levels, does not establish that the claim is about blood LDL cholesterol levels that are already within normal limits and, therefore, implies that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Your submission also states that the product will use the claim "The high potency Omega-3 Fatty Acids from fish oil, including EPA and DHA, have been shown in numerous clinical trials to provide benefits for cardiovascular health. Fish oil

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concentrates have been shown to support healthy triglyceride levels, and reduce risk factors." This statement is not a statement of nutritional support subject to 21 U.S.C. 343(r)(6), but is a health claim subject to 21 U.S.C. 343(r)(1)(B). On October 31, 2000 and February 16, 2001¹, in response to the court decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), FDA issued letters that set forth the conclusions reached by the agency in its reconsideration of a claim for the relationship between the consumption of omega-3 fatty acids the risk of coronary heart disease. The letters set forth conditions, consistent with, and in addition to, those described in the Pearson implementation notice (published in the October 6, 2000 Federal Register; 65 FR 59,855), under which it intends to exercise enforcement discretion with respect to the use of the qualified claim, as described above, on EPA and DHA omega-3 fatty acid dietary supplements. The claim you intend to make does not appear to be consistent with the qualified claims that the agency discussed in the letters cited above. A dietary supplement bearing a claim that is not properly qualified, as described in the letters cited above, or consistent with the weight of the evidence is subject to regulatory action as a misbranded food under section 403(a)(1) and 403(r)(1)(B) of the Act, a misbranded drug under section 502(f)(1), and as an unapproved new drug under section 505(a).

Please contact us if we may be of further assistance.

Sincerely yours,

for Robert Moore

John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

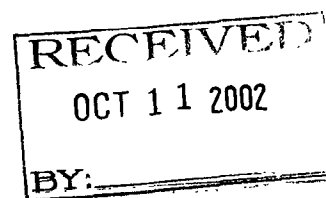
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Los Angeles District Office, Office of Compliance, HFR-PA240

¹ Copies of these letters are available on our web site: <http://www.cfsan.fda.gov/~dms/ds-ltr11.html>
and <http://www.cfsan.fda.gov/~dms/ds-ltr20.html>.



September 26, 2002



Office of Nutrition Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
Harvey W. Wiley Building
HFS-810
College Park, MD 20740

Re: Section 403(r)(6) Dietary Supplement Notification

To Whom It May Concern:

Pursuant to Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA) we are notifying the Food and Drug Administration (FDA) that we have introduced into interstate commerce a dietary supplement that contains a structure/function claim. We are providing the following information as required by 21 CFR 101.93(a)(2):

1. Name and Address of the Manufacturer:

Vital Living
5080 N. 40th Street; Ste 105
Phoenix, AZ 85018-2147
United States
602-952-9909 Phone
602-952-6907 Fax

2. Text of the Statements:

The following statements appear on the label of Essentium®:

Folate, Pyridoxine (B6) and Cyanocobalamin (B12) have been demonstrated to promote optimal plasma homocysteine levels, contributing to cardiovascular health.*

Niacin is proven to promote healthy levels of desirable HDL cholesterol while supporting LDL and triglyceride levels*.

The high potency Omega-3 Fatty Acids from fish oil, including EPA and DHA, have been shown in numerous clinical trials to provide benefits for cardiovascular health. Fish oil concentrates have been shown to support healthy triglyceride levels, and reduce risk factors.*

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* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease

3. Name of the Dietary Ingredient

Each package of Essentum® contains four different capsules that are to be taken twice per day. Essentum® contains the following five capsules:

- A multivitamin and mineral capsule including (Folate, Pyridoxine (B6) and Cyanobalamin (B12)); A Niacin capsule;
- An Omega-3 Fatty Acids capsule; and
- Two Plant Sterols capsules

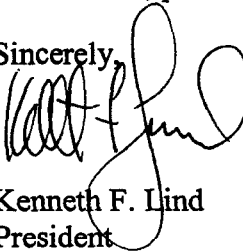
4. Name of the Dietary Supplement

Essentum®

I certify that the information contained in the notice is complete and accurate, and that Vital Living has substantiation that the statements are truthful and not misleading.

If you have any questions on this or other matters, please contact us.

Sincerely,



Kenneth F. Lind
President